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FEB - 6 2006

Grover F. Fuller, Jr.  
Pfizer, Inc.  
Legal Division  
235 East 42nd Street  
New York NY 10017-5755

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,831,031

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,831,031, which claims the human drug product GEODON® (ziprasidone HCl monohydrate) and a method of its use, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of April 29, 2005 (70 Fed. Reg. 22341), would be 2,678 days (7.3 years). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,511 \text{ days}) + 1,422 \text{ days} \\ &= 2,678 \text{ days (7.3 years)}\end{aligned}$$

Since the regulatory review period began May 3, 1990, after the patent issued (May 16, 1989), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,831,031

Granted: May 16, 1989

Original Expiration Date<sup>1</sup>: March 2, 2007  
Applicant: John A. Lowe, III, et al.  
Owner of Record: Pfizer Inc.  
Title: ARYL PIPERAZINYL-(C<sub>2</sub> OR C<sub>4</sub>)ALKYLENE HETEROCYCLIC COMPOUNDS HAVING NEUROLEPTIC ACTIVITY  
Product Trade Name: GEODON® (ziprasidone HCl monohydrate)  
Term Extended: Five years  
Expiration Date of Extension: March 2, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. By FAX: (571) 273-7755  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

Kery A. Fries  
Kery Fries  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Office of Regulatory Policy RE: GEODON® (ziprasidone HCl monohydrate)  
HFD - 13 FDA Docket No.: 03E-0259  
5600 Fishers Lane  
Rockville, MD 20857  
  
Attention: Claudia Grillo

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).